UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,858	09/26/2005	Syunichi Akiba	278162US0PCT	3593

22850 7590 05/27/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HOFFMAN, SUSAN COE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
05/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,858	AKIBA ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-12* is/are pending in the application.

4a) Of the above claim(s) *6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 2, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. The declaration of Shunichi Akiba, submitted July 24, 2008, has been considered.

3. Claim 5 has been cancelled in this amendment.

4. Claims 7-12 have been added in this amendment.

5. Claims 1-4 and 6-12 are pending.

Election/Restrictions

6. In the reply filed on March 6, 2008, applicant elected Group I, now claims 1-4 and 9-12, with traverse. In the interview of April 3, 2008, applicant elected phellodendron for the species with traverse.

7. Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

8. Newly submitted claims 7 and 8 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 7 and 8 lack unity with claims 1-4 and 9-12. This is demonstrated by the 102 references applied below that teach the claimed Phellodendron bark extract but do not teach a method of making a product by adding this extract to a deodorant composition or using this extract in a method for inhibiting the decomposition of apolipoprotein D.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 7 and 8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

9. Claims 1-4 and 9-12 are examined on the merits solely in regards to the elected species of Phellodendron.

Claim Rejections - 35 USC § 112

10. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite because it states that the agent comprises "0.00001 to 10 wt.%" but does not state what this percentage is referring to. It is unclear if this percentage is referring to the amount of the active ingredient in the deodorant agent. In addition, it is unclear if this percentage is referring to the solid content of the entire deodorant agent or the active agent.

Claim Rejections - 35 USC § 102

11. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (Igaku to Seibutsugaku (1994), vol. 128, no. 3, pp. 121-6).

This reference teaches a phellodendron bark extract made by extracting the plant with 95% ethanol (see English abstract). The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference

composition would inherently have to have the same effects if applicant's invention functions as claimed.

12. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1137905.

This reference teaches a phellodendron bark extract made by extracting the plant with 95% ethanol (see English abstract). The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1076622.

This reference teaches a phellodendron bark extract made by extracting the plant with 90% ethanol (see English abstract). The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-4 and 9-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ishino (WO 02/051374 - US 2004/0047833 is the English translation of WO '374 - US '833 will be referenced in the rejection).

Claims 1-4 and 9-12 are product-by-process claims. Regarding product-by-process claims, note that MPEP § 2113 states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate…A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)… Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

Ishino teaches a phellodendron bark extract made by extracting the plant material with 70% ethanol. The extraction can be carried out at 20 degrees C. The extract is added to topical composition in an amount from 0.000001 to 5% by weight (see paragraphs 12, 15, 28 and 29). Thus, the reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are from the same plant, are extracted using high concentrations of ethanol and are same for topical use. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics. In addition, an artisan of ordinary skill would reasonably expect that the concentration of the solvent would be a result effective parameter. An artisan of ordinary skill would be motivated to modify the concentration of the solvent during routine optimization of experimental parameters.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

It is noted that applicant's arguments submitted March 2, 2009 state that the declaration of Mr. Akiba shows that the concentration of ethanol produces unexpected results. However, the results in the declaration compare extracts made using 50% versus 95% aqueous ethanol. The results do not show any other concentrations of aqueous ethanol. Thus, the results shown are not considered to show unexpected results over the entire scope of ethanol concentrations claimed or show unexpected results in comparison with the ethanol concentration used in Ishino.

Claim Rejections - 35 USC § 103

15. Claims 1-4 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN 1076622.

The teachings of this reference are discussed above. The reference does not specifically teach using all of the alcohol concentrations and extraction temperatures claimed by applicant.

The solvent concentration and extraction temperatures are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). An artisan of ordinary skill would routinely modify the extraction parameters in order to form an extract with the most desirable characteristics. Therefore, an artisan would have been motivated to modify the solvent concentration and extraction temperature in order to create a product that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of parameters would have been obvious at the time of applicant's invention.

The reference also do not specifically teach adding the phellodendron extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that the phellodendron extract is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from

the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

16. Claims 1-4 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN 1137905.

The teachings of this reference are discussed above. The reference does not specifically teach using all of the alcohol concentrations and extraction temperatures claimed by applicant. The solvent concentration and extraction temperatures are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). An artisan of ordinary skill would routinely modify the extraction parameters in order to form an extract with the most desirable characteristics. Therefore, an artisan would have been motivated to modify the solvent concentration and extraction temperature in order to create a product that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of parameters would have been obvious at the time of applicant's invention.

The reference also do not specifically teach adding the phellodendron extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that the phellodendron extract is

a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Double Patenting

17. Claims 1-4 and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,501,136. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to compositions which contain phellodendron extracts. The claims of US '136 teach using between 0.0001 to 5% of the phellodendron extract. The claims of US '136 teach using the hydrophobic fraction of the phellodendron. Preparation Example 2 defines the hydrophobic fraction as a fraction of the phellodendron bark created using a method comprising adding 95% ethanol to the bark of the plant and extracting at room temperature. The example adding 100 mL of ethanol / 10 g of the bark ("those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970) - MPEP section

804, II-B-1). Thus, the claims of the patent anticipate the stated claims despite a difference in scope.

18. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655